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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS SUBSTANTIAL EQUIVALENCY

Submitter: Address:	Surgical Specialties Corporation dba Angiotech 100 Dennis Drive Reading, PA 19606
Telephone: Contact Person:	610 404 1000, ext. 2231 Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	December 6, 2006 revised May 07, 2007
Name of Device:	Sharpoint® PDO (Polydioxanone) Synthetic, Absorbable, Monofilament Sutures
Common / Usual Classification Name: Regulation Number: Device Classification:	Surgical Suture. Absorbable Polydioxanone Surgical Suture. 878.4840 Class II Device
Predicate Device:	Ethicon's PDS II Submission Number N18331
Device Description	The Sharpoint® (Polydioxanone) PDO Suture is a synthetic, absorbable, monofilament surgical suture available dyed D&C violet No.2. The PDO Sutures are attached to various size needles made of 400 series stainless steel.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Intended Use:	The Sharpoint® PDO Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.
Technological Characteristics:	The Polydioxanone material is well characterized through absorption studies and biocompatibility studies. Bench testing has demonstrated the device to be safe and effective. Its performance is equivalent to the predicate device, Ethicon PDS II.
Performance Data:	Physical testing was performed on PDO (Polydioxanone) Synthetic, Absorbable sutures to USP 29, including <861> Suture Diameter, <871> Suture Attachment, <881> Tensile Strength. Animal testing was performed for conformance to ISO 10993 for Biocompatibility and Implant studies to demonstrate rates of tensile and mass loss.
Substantial Equivalency:	The Sharpoint® PDO sutures are equivalent to the predicate device PDS II in material composition, intended use, absorption profile and bench testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Specialties Corporation
dba Angiotech
% Ms. Elizabeth Lazaro
Regulatory Affairs Specialist
100 Dennis Drive
Reading, Pennsylvania 19606

MAY - 9 2007

Re: K063680
Trade/Device Name: Sharpoint® PDO Sutures
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW
Dated: April 19, 2007
Received: April 20, 2007

Dear Ms. Lazaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

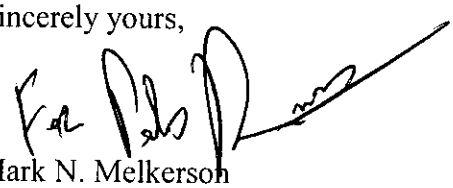
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063680

Indications for Use

510(k) Number (if known):

Device Name: Sharpoint® PDO Sutures

Indications For Use:
Sharpoint® PDO sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular, or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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